ABBOTT RECEIVES WHO PREQUALIFICATION APPROVAL FOR BREAKTHROUGH HIV POINT-OF-CARE TEST

- WHO Prequalification approval allows Abbott to bring critical technology to more resource-limited settings

- Confirms that the m-PIMA™ HIV-1/2 VL meets global standards of quality, safety and efficacy

ABBOTT PARK, Ill., May 2, 2019 /PRNewswire/ -- Abbott (NYSE: ABT) announced today that m-PIMA™ HIV-1/2 VL, the world's first point-of-care viral load diagnostic test, has received the World Health Organization's Prequalification approval (WHO PQ). The test received CE Mark in December 2018.

"m-PIMA HIV-1/2 VL is the only truly portable molecular point-of-care test designed specifically for use in resource-limited settings such as in sub-Saharan Africa," said Damian Halloran, vice president, Infectious Disease – Emerging Markets, Rapid Diagnostics, Abbott. "With WHO PQ, global funders and ministries of health can now confidently expand access to viral load testing, reaching more people who need the test, with the most compact and efficient point-of-care HIV diagnostic platform available anywhere in the world today."

To provide the most effective HIV treatment and care, the WHO recommends that everyone receiving antiretroviral therapy (ART) undergoes a viral load test at 6 months and 12 months, and annually thereafter, if the individual is stable on ART. Viral load testing is the gold standard for monitoring ART treatment failure.[1] Unfortunately, very few people[2] in resource-limited settings, such as select countries in sub-Saharan Africa, Asia and Latin America, have access to the necessary level of care.

Abbott's m-PIMA HIV-1/2 VL is a quantitative nucleic acid amplification test for viral load measurement of HIV type 1 groups M/N and O, and HIV-2 in plasma samples. The platform is portable so it can be brought into the most remote locations. It's easy to use, deployable at the point of care and designed to measure viral load in under 70 minutes, while the patient is still present. This allows people to receive results during the same visit and enables immediate treatment decisions, thereby reducing the number of people lost to follow-up. The test's quick turnaround time is particularly valuable for monitoring the viral load of HIV-positive pregnant women and in cases of suspected HIV treatment failure.

The m-PIMA HIV-1/2 VL is part of Abbott's comprehensive portfolio of diagnostic solutions for HIV screening, monitoring and viral load management. From the core lab to the point of care, Abbott provides critical tools to help healthcare providers make informed treatment decisions for people living with HIV.

About WHO Prequalification (PQ)
WHO Prequalification (PQ) aims to ensure that diagnostics, medicines, vaccines and immunization-related equipment and devices for high burden diseases meet global standards of quality, safety and efficacy, to optimize use of health resources and improve health outcomes.

The prequalification process consists of a transparent, scientifically sound assessment, which includes dossier review, consistency testing or performance evaluation and site visits to manufacturers. This information, in conjunction with other procurement criteria, is used by UN and other procurement agencies to make purchasing decisions regarding diagnostics, medicines and/or vaccines.

For more information, go to https://www.who.int/topics/prequalification/en/.

About Abbott
Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 103,000 colleagues serve people in more than 160 countries.

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[1] Roberts, T., Cohn, J., Bonner, K., & Hargreaves, S. (2016). Scale-up of Routine Viral Load Testing in Resource-Poor Settings: Current and Future Implementation Challenges. Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America, 62(8), 1043-1048. http://doi.org/10.1093/cid/ciw001

[2] UNAIDS (2014) 90-90-90 An ambitious target to help end the AIDS epidemic. Available on http://www.unaids.org/sites/default/files/media_asset/90-90-90_en_0.pdf

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